

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

JEFFREY D. FISHER, Individually and on
Behalf of All Others Similarly Situated,

Plaintiff,

v.

FENNEC PHARMACEUTICALS INC.,
ROSTISLAV RAYKOV, and ROBERT
ANDRADE,

Defendants.

Case No. 1:22-cv-00115-CCE-JLW

[Amended] Complaint -- Class Action

Judge Catherine C. Eagles

Magistrate Judge Joe L. Webster

JURY TRIAL DEMANDED

Lead Plaintiff Jeffrey D. Fisher (“Plaintiff”), individually and on behalf of all others similarly situated, by Plaintiff’s undersigned attorneys, for his amended complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of Defendants’ public documents, conference calls and announcements made by Defendants, United States (“U.S.”) Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Fennec Pharmaceuticals Inc. (“Fennec” or the “Company”), analysts’ reports and advisories about the Company, interviews with knowledgeable former employees of the Company and/or affiliated entities, and information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. Fennec, a late clinical stage biotech company, is focused on a single therapy – a

medicine called PEDMARK™ (“PEDMARK”) which purports to prevent ototoxicity (or damage to the ear) associated with the use of cisplatin – a chemotherapy drug – by children with certain solid tumors.

2. During the Class Period – May 28, 2021 through November 26, 2021, both dates inclusive – Fennec’s lead product candidate and core focus was PEDMARK.

3. Defendants misled investors with respect to Fennec’s ability to achieve approval from the United States Food and Drug Administration (“FDA”) for its New Drug Application (“NDA”) for PEDMARK by knowingly or recklessly failing to disclose known material deficiencies related to its third-party drug manufacturer, the Maryland-based Pharmaceutics International, Inc. (“PII”).

4. PII was a manufacturer with a history of multiple serious deficiencies identified in prior FDA inspections, of inadequate corrective measures after deficiencies were identified, as well as drug recalls.

5. Prior to the start of the Class Period, in August 2020, the FDA rejected the PEDMARK NDA, issuing a Complete Response Letter (“CRL”)¹ after PII failed inspection due to deficiencies at its manufacturing facility. As a result, the FDA’s anticipated approval of PEDMARK was delayed.

6. At that time, and all relevant times thereafter, Defendants were in direct, continuous communication with PII concerning their PEDMARK-related manufacturing activities.

7. On May 28, 2021, the date which marks the start of the Class Period, Fennec announced that it had resubmitted the PEDMARK NDA with the FDA (the “Resubmitted

¹ The FDA sends a pharmaceutical company a CRL if the agency determines that it will not approve the company’s NDA in its present form.

PEDMARK NDA”).

8. Defendants either failed to conduct adequate due diligence into Fennec’s third-party product manufacturer, PII, or, even worse, ignored the fact that PII was non-compliant with essential good manufacturing practices and thus would likely not pass FDA muster.

9. Hence, analysts and investors had been led to believe that Fennec had overcome a minor manufacturing hiccup, and that FDA approval was “*not a question of ‘if’, but ‘when’*”.² Or, as the investor site *Seeking Alpha* optimistically put it in July 2021, “*Fennec and its contract manufacturer should easily have addressed [the manufacturing-related issues] by now.*”³

10. But Defendants had done no such thing, and any market sentiment to the contrary was the product of Defendants’ own numerous distortions of the truth about PII’s manufacturing activities on Fennec’s behalf, including the false claims that the problem “*had been addressed*”, that the FDA had greenlit PII’s facility by accepting the PEDMARK NDA, and that Fennec had a “backup” manufacturer lined up and ready to assume that role in the event that PII was disqualified. None of this was true.

11. In sum, Defendants abused the confidentiality surrounding new drug approval process to mislead the market about the strength of their ability to manufacture PEDMARK.

12. Specifically, Defendants, throughout the Class Period, made materially false and misleading statements and/or failed to disclose that: (i) manufacturing deficiencies still existed at PII during the Class Period; (ii) Defendants had failed to conduct adequate due diligence into PII; (iii) Defendants had not verified that deficiencies at PII were resolved; (iv) Defendants had not

² Naureen Quibria, Ph.D., Jason McCarthy, Ph.D., *Reports the Quarter, On Track for NDA Resubmission in 2Q21 – Maintain Buy*, MAXIM GROUP (May 13, 2021).

³ Andy Jones, *Fennec Could See Upside If Pedmark Gets Approved*, SEEKING ALPHA (July 29, 2021), <https://seekingalpha.com/article/4442781-fennec-stock-could-see-upside-if-pedmark-gets-approved>.

procured evidence establishing that “the methods used in manufacturing the drug and the controls used to maintain the drug’s quality are adequate to preserve the drug’s identity, strength, quality, and purity,” as FDA regulations require for approval; (v) therefore, Defendants had not established a basis for approval of the Resubmitted PEDMARK NDA; and (vi) as a result, the Company’s public statements were materially false and misleading at all relevant times.

13. On November 29, 2021, during pre-market hours, Fennec issued a press release “announc[ing] that it expects to receive a [CRL] after the PDUFA [Prescription Drug User Fee Act] target action date of November 27, 2021 from the [FDA] regarding its [Resubmitted Pedmark NDA].”

14. Fennec advised investors that “*[t]he FDA has indicated that, following a recent completion of a pre-approval inspection of the manufacturing facility of our drug product manufacturer, deficiencies have been identified[.]*”⁴ and that “[o]nce the official CRL is received, the Company plans to request a Type A meeting to discuss the deficiencies and steps required for the resubmission of the NDA for PEDMARK™.”

15. Then, on November 30, 2021, Fennec confirmed that it had received a CRL from the FDA, which “*was issued as a result of identified manufacturing deficiencies which need to be satisfactorily resolved before the Pedmark NDA can be approved.*”⁵ In addition, Fennec’s CEO, Rostislav Raykov, noted that while Fennec “*[w]ill work closely with [its] current manufacturer as well as the FDA to fully address the issues raised in the letter[.]*” we continue to

⁴ Emphasis added throughout, unless otherwise noted.

⁵ *Fennec Pharmaceuticals Receives Complete Response Letter From the FDA for Its New Drug Application for Pedmark™ to Prevent Ototoxicity Associated With Cisplatin in Pediatric Patients With Localized, Non-Metastatic, Solid Tumors*, FENNEC PHARMACEUTICALS, INC. (Nov. 30, 2021), *see* <https://investors.fennecpharma.com/news-releases/news-release-details/fennec-pharmaceuticals-receives-complete-response-letter-fda-0>.

advance our second drug product manufacturing facility.”

16. On the heels of the November 29 and 30, 2021 disclosures, the Company’s stock price plummeted by **more than 59%** to close at \$3.89 on December 1, after three days of heavy trading, thereby damaging Plaintiff and other Class members.

17. PEDMARK has yet to be approved by the FDA or any regulatory authority, for that matter.

JURISDICTION AND VENUE

18. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

19. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

20. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Fennec is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants’ actions took place within this Judicial District.

21. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

22. Plaintiff, as set forth in his previously-filed Certification (ECF No. 16-4), which is incorporated by reference herein, acquired Fennec securities at artificially-inflated prices during

the Class Period and was damaged upon the revelation when true facts about the Company's business operations and future prospects were disclosed. Pursuant to the Private Securities Litigation Reform Act of 1995, Plaintiff was appointed to serve as Lead Plaintiff in the above-captioned action by Order of this Court dated May 9, 2022 (ECF No. 20).

23. Defendant Fennec is organized under the laws of British Columbia, Canada, with principal executive offices located at PO Box 13628, 68 TW Alexander Drive, Research Triangle Park, North Carolina 27709. Fennec's common shares trade in an efficient market on the Nasdaq Capital Market ("NASDAQ") under the trading symbol "FENC".

24. Defendant Rostislav Raykov ("Raykov") was, at all relevant times, a director and Fennec's Chief Executive Officer ("CEO").

25. Defendant Robert Andrade ("Andrade") was, at all relevant times, Fennec's Chief Financial Officer ("CFO").

26. Defendants Raykov and Andrade are sometimes referred to herein as the "Individual Defendants."

27. The Individual Defendants, because of their positions with the Company, had access to non-public information about the Company's business operations and prospects, financial condition, markets, and meetings and communications with the FDA and/or third-parties via access to internal corporate documents, conversations, and connections with other corporate officers and employees, attendance at management and/or Board meetings and committees thereof, and *via* reports and other information provided to them in connection therewith.

28. As such, the Individual Defendants had access to material adverse non-public information concerning Fennec's ability to achieve FDA approval of the PEDMARK NDA and the quality and capabilities of its third-party drug manufacturers, as discussed in detail below.

Because of their possession of such information, the Individual Defendants knew or recklessly disregarded the fact that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

29. The Individual Defendants are liable as direct participants in the wrongs complained of herein. The Individual Defendants participated in the drafting, preparation, and/or approval of the various public, shareholder, and investor reports and other communications complained of herein and were aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom, and were aware of the materially misleading nature of these documents. Each of the Individual Defendants had access to the adverse undisclosed information about Fennec's ability to achieve approval from the FDA for its PEDMARK NDA and the quality and capabilities of its third-party drug manufacturers as particularized herein, and knew or recklessly disregarded that these adverse facts rendered the positive representations made by or about Fennec and its business, which were issued or adopted by the Company, materially misleading.

30. Fennec and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

A. Relevant FDA New Drug Application Requirements

31. Enacted in 1938, the Food, Drug and Cosmetic Act ("FDCA") created the FDA, an agency of the United States Department of Health and Human Services, to "protect the public health" by ensuring that "drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). The FDCA provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to [this section] is effective with

respect to such drug.” 21 U.S.C. § 355(a).

32. Accordingly, new pharmaceutical drugs – such as PEDMARK – must receive FDA approval prior to sale, marketing, and commercial distribution in the United States. Drug “sponsors” (*i.e.*, applicants, such as Fennec) seek approval from the FDA through the FDA’s New Drug Application (NDA) process. The NDA process has been designed to provide information to permit the FDA to determine whether: (i) the drug is safe and effective in its proposed use(s), and the benefits of the drug outweigh the risks; (ii) the drug’s proposed labeling (package insert) is appropriate, and what it should contain; and (iii) ***the methods used in manufacturing the drug and the controls used to maintain the drug’s quality are adequate to preserve the drug’s identity, strength, quality and purity.***⁶

33. The NDA process includes adequate and well-controlled human clinical trials to establish the efficacy of the drug for each indication. 21 C.F.R. § 314.126.

34. Chemistry, Manufacturing and Controls (“CMC”) is an integral part of any pharmaceutical NDA submitted to the FDA. CMC applies to the entire product lifecycle – beginning during Phase I clinical trials, continuing through post-approval and beyond. CMC ensures that pharmaceutical drug products are consistently effective, safe and high quality for consumers. It sustains a connection between the drug that is used in clinical studies and the commercial drug that is marketed and available to consumers. ***CMC applies to both the drug itself and the facility in which the drug is being manufactured.***

35. A sponsor or manufacturer may choose to make changes during the drug development process, such as a new manufacturing site, however, when changes are made to the

⁶ U.S. FOOD & DRUG ADMIN., NEW DRUG APPLICATION (NDA) (“FDA NDA”) (June 10, 2019), <https://www.fda.gov/drugs/types-applications/new-drug-application-nda>.

manufacturing process, the sponsor and/or manufacturer must demonstrate that the changes will not have an adverse impact on the quality, safety, and efficacy of the drug product.⁷

36. For example, manufacturing changes due to a site-transfer requires additional site-specific stability data (“SSS data”). To determine the amount of SSS data needed, the potential for an adverse impact is assessed on a three-tiered risk-based system, examining the timing of the change, the drug substance makeup and the drug product form. *Id.*

37. Prior to submitting an NDA filing, the FDA will conduct a pre-submission meeting with the sponsor to discuss possible filing and format issues, *including confirmation that all facilities (e.g., manufacturing, testing, packaging) will be ready for inspection by the time of the NDA submission.*⁸

38. After successful completion of the required clinical testing, the preclinical study and clinical trial results are submitted to the FDA as part of an NDA to support approval to market a drug for one or more indications, along with detailed information regarding the drug or treatment’s CMC and proposed labeling, among other things.

39. The FDA must conduct a preliminary review of an NDA within 60 days after submission to determine whether it is sufficiently complete to permit a substantive review. If the FDA accepts the NDA for filing, it begins the substantive review process, reviewing the NDA to determine, among other things, whether the drug is safe and effective for its intended use and *whether the facility in which it is manufactured, processes, packaged or held meets standards*

⁷ U.S. FOOD & DRUG ADMIN., CHANGES TO AN APPROVED NDA OR ANDA – GUIDANCE FOR INDUSTRY (April 2004), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-approved-nda-or-anda>.

⁸ U.S. DEPT. OF HEALTH AND HUMAN SERVICES, GUIDANCE FOR INDUSTRY (May 2001), <https://www.fda.gov/files/Guidance-for-Industry---IND-Meetings-for-Human-Drugs-and-Biologics---Chemistry-Manufacturing-and-Controls-Information-%28PDF%29.pdf>.

designed to assure the product's continued safety, quality and purity.

40. As part of the NDA process, a drug sponsor must provide the FDA with sufficient information to reach a decision as to “[w]hether the **methods used in manufacturing** the drug **and the controls used to maintain the drug's quality** are adequate to preserve the drug's identity, strength, quality, and purity.” 505(b)(1)(D), 21 C.F.R. § 314.50(d)(1)(i).

41. The FDA ensures a drug's quality by monitoring the drug manufacturer(s)' compliance with the FDA's Current Good Manufacturing Practice (cGMP) regulations. *The cGMP regulations contain requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug to ensure that it is safe for use and has the ingredients and strength it claims to have.*

42. As such, *the NDA review process includes an examination of the drug manufacturer's compliance with the cGMP regulations and a determination of whether it has the necessary facilities, equipment, and ability to manufacture the drug.* *Id.* To assist in that determination, the FDA performs a pre-approval inspection (“PAI”). The FDA may inspect all facilities associated with a submission.

43. *Since the goal is to confirm that the manufacturer named in an NDA is capable of manufacturing the drug*, and that the submitted data is accurate and complete, the FDA's three main objectives for the PAI are to: *(i) assess readiness for commercial manufacturing*, *i.e.* determine if the manufacturer(s) has a quality system designed to achieve sufficient control over the facility and commercial manufacturing operations; *(ii) assess conformance to the application*, *i.e.*, verify that the formulation, manufacturing or processing methods, and analytical (or examination) methods, are consistent with descriptions in the NDA; and *(iii) conduct a data integrity audit*, *i.e.*, audit the raw data (hardcopy or electronic) to authenticate the submitted data

and verify that all relevant data was submitted such that the FDA could rely on the data as complete and accurate.⁹

44. *When conducting a PAI, trained investigators tour the facility with the facility's staff and the drug sponsor, look for significant deviations from the FDCA and other acts where the FDA has enforcement authority, and take note of factual observations that, in their judgment, constitute violations of FDA standards. Any reportable inspection observations are presented and explained to the facility's management and the drug sponsor at an exit interview on the last day of the inspection, and then recorded in a Form 483 (discussed below) issued to the facility after the exit interview. FDA Investigators and analysts make every reasonable effort to discuss all observations with facility management and the drug sponsor as they are observed or on a daily basis, to minimize surprises, errors and misunderstandings when the Form 483 is issued. Id.*

45. Reportable inspection observations warranting a Form 483 include:

- PAI findings reflecting differences from the filed CMC description for bio-batch, or stability batches, such that the proposed commercial batch record does not assure a reproducible manufacturing operation.
- PAI list of differences from filed CMC description of formulations, processing principles, equipment use, or discrepancies in raw material lot reconciliation (*i.e.* inconsistencies in records for receipt, inventory, or use in production).
- Missing or unreliable data in that the data/information submitted was potentially unreliable or misleading or there were unexplained or inappropriate gaps in a chromatographic or analytical sequence.
- A pattern of inappropriately disregarded test results and/or inadequate or lack of justification for not reporting data/information.
- Insufficiency, discrepancy, or failing of an analytical method validation

⁹ U.S. FOOD & DRUG ADMIN., Compliance Program 7346.832, Chapter 46-New Drug Evaluation (Sept. 16, 2019), <https://www.fda.gov/media/121512/download>.

program.

- Lack of suitability of the facility, equipment or manufacturing operations intended for making the commercial API or finished product to the cGMP regulations.
- Other specific non-conformance (e.g., conditions, practices, procedures) with the cGMP regulations.

46. All observations recorded in a Form 483 are significant and correlate to regulated products or processes being inspected. Facility management has 15 days to provide written responses to the Form 483 observations.

47. If the FDA does not approve an NDA, it will send the sponsor a CRL, which describes all the specific deficiencies that the FDA identified in the NDA and when possible, recommends actions that the sponsor could take to place its NDA in condition for approval, and A sponsor may resubmit its NDA.

B. Fennec's Development of PEDMARK

48. Fennec is a biopharmaceutical company that develops product candidates for use in the treatment of cancer in the U.S. The Company's lead product candidate is PEDMARK, a formulation of Sodium Thiosulfate ("STS"), which has completed a Phase III clinical trial for the prevention of cisplatin induced hearing loss, or ototoxicity, in children.

49. FDA granted PEDMARK Orphan Drug Designation in 2004. The Orphan Drug Act provides for granting special status to a drug to treat a rare disease or condition, but that status does not alter the standard regulatory requirements and process for obtaining marketing approval.

50. In 2013, Fennec acquired an exclusive worldwide license agreement with Oregon Health & Science University ("OHSU") for the intellectual property directed to thiol-based compounds including STS and their use in oncology.

51. Starting in 2018, Fennec repeatedly stated in SEC filings PEDMARK "***is our only***

lead product candidate in the clinical stage of development” and therefore “*d[id] not expect to have significant revenues from our product candidate until we are either able to sell our product candidate after obtaining applicable regulatory approvals or we establish collaborations that provide us with up-front payments, licensing fees, milestone payments, royalties or other revenue.*” As such, Fennec “*continue[s] to focus* the Company’s resources *on the development of PEDMARKTM*

52. In December 2018, Fennec initiated a rolling NDA with the FDA for PEDMARK for the prevention of ototoxicity induced by cisplatin chemotherapy in patients 1 month to < 18 years of age with localized, non-metastatic, solid tumors (the “Initial Pedmark NDA”). In that same month, Fennec participated in its pre-submission meeting with the FDA.

C. Defendants Recklessly Contract With PII

53. While Fennec has never publicly-disclosed the identity of the third-party manufacturer(s) with which it contracted, Plaintiff’s investigation has confirmed that Fennec contracted with PII to be the drug product manufacturer for PEDMARK no later than December 2018.

54. PII, which had two facilities in close proximity to one another in, respectively, Hunt Valley, Maryland and Cockeysville, Maryland (the “Cockeysville Facility”), boasts a long history of regulatory misfeasance predating its engagement by Fennec. For example –

- According to a June 15, 2016 news article on the site *fiercepharma.com*, the European Medicines Association (“EMA”) announced that Pii’s manufacturing certification is being pulled and a recall has been recommended due to the above deficiencies identified by the MHRA.¹⁰

¹⁰ <https://www.fiercepharma.com/manufacturing/u-k-regulator-bans-products-from-u-s-cmo-pii>

- a June 17, 2016 report by the EMA referenced a joint inspection of PII's Maryland facilities by the MHRA and the FDA, which found that the “corrective and preventative measures had not been appropriately implemented and that critical and major GMP deficiencies remained” following an earlier inspection, including:
 - “Critical deficiencies relating to the failure of organizational and technical measures to minimize the risk of cross-contamination between hazardous and non-hazardous products manufactured in the same manufacturing facilities using shared equipment, as well as failures of the quality unit to ensure operation of the quality system.”¹¹
 - “Major deficiencies relating to the organizational data governance failures, sterilization and depyrogenation processes, and insufficient control of aseptic operations to provide the required level of sterility assurance.”¹²
 - As a result of the above findings, European regulators prohibited PII from shipping drugs to Europe, stating that (i) “*[t]he supply of medicines is now restricted in the EU*”; (ii) “*recall of batches is recommended*”; and (iii) *future batches will no longer be supplied from this site unless they are considered to be critical to public health.*¹³
- On October 20, 2016, fiercepharma.com published an article about Teva recalling 43,000 bottles of paricalcitol, a drug used by dialysis patients, that were produced by PII. The recall had started several weeks earlier “*because the products failed stability testing for*

¹¹ https://www.ema.europa.eu/en/documents/referral/pharmaceutics-international-inc-article-31-referral-notification_en.pdf

¹² *Id.*

¹³ *Id.*

impurity levels," the article stated.¹⁴

55. Unsurprisingly, PII received a Form 483 for both its facilities based on inspections which took place July 6-10, 2020, while it was under contract as Fennec's drug product manufacturer for PEDMARK.

56. In particular, the FDA observed the following cGMP deficiencies observed at the Cockeysville Facility:

- (1) Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design and of adequate size to facilitate operations for its intended use, which "diminishes sterility assurance of drug products manufactured."
- (2) Equipment and utensils are not maintained at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.
- (3) Equipment for adequate control over micro-organisms is not provided when appropriate for the manufacture, processing, packing or holding of a drug product. Specifically, the Cockeysville Facility "failed to adequately demonstrate unidirectional airflow over critical aseptic equipment" used in the manufacturing of PEDMARK.
- (4) Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations. The FDA specifically commented "that all these findings indicate a lack of attention to the condition of facilities and equipment and that the observed conditions could lead to ingress of microorganisms, insect pests, and other contaminants to the cleanrooms and support areas and result in contamination of the firm's drug products."
- (5) Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

57. In August 2020, Fennec announced that it had received a CRL from the FDA for the Initial PEDMARK NDA, stating that "after recent completion of a pre-approval inspection of the manufacturing facility of our drug product manufacturer, the FDA identified deficiencies

¹⁴ <https://www.fiercepharma.com/manufacturing/pii-problems-result-teva-recall>

resulting in a Form 483, which is a list of conditions or practices that are required to be resolved prior to the approval of PEDMARK™.”

58. The former CEO at PII from January 2019 to March 2022 (Former Employee ([“FE”] 1”) confirmed that PII informed Fennec about the results of the FDA’s inspection of the manufacturing facilities in July 2020.

59. FE1 further confirmed that Fennec was provided the inspection report and the Form 483 listing the deficiencies related to the 2020 FDA inspection.

60. FE1 further revealed that PII had conversations with Fennec about how it planned to address the deficiencies identified by the FDA in 2020 and when remediation of those deficiencies would be complete.

61. Finally, FE1 disclosed that PII kept the FDA updated on the progress to address the deficiencies so that the FDA would know when to return for another inspection.

62. The former Director of Quality Control at PII from November 2019 to January 2021 (“FE2”) worked in the testing lab at PII’s Hunt Valley, Maryland facility, which is in a complex of buildings directly down the street from the Cockeysville Facility.

63. FE2 reported to Monique Mendoza, Head of Quality at PII.

64. FE2 confirmed that PII was making Fennec’s drug PEDMARK (Sodium Thiosulfate) at the Cockeysville Facility.

65. FE2 further confirmed that PII received a substantial number of Forms 483 during FE2’s time there.

66. While FE2 noted, that it is a drug sponsor’s responsibility to audit and inspect CMO facilities independent of the FDA to ensure that the manufacturing facility is meeting all requirements and good manufacturing practices that the FDA will inspect prior to approving an

NDA, FE2 did not recall Fennec undertaking any audit or inspection of the PII facility where PEDMARK was made after the FDA's July 2020 inspection, to ensure PII was fixing the deficiencies.

67. Still, the market remained blissfully unaware of Defendants' lack of due diligence. On March 30, 2021, just before the start of the Class Period, Cantor Fitzgerald analysts dismissed the possibility that the history embodied by the 2020 CRL would repeat itself:

.... we do not believe the CRL represents a “fatal flaw” in the clinical package supporting PEDMARK, nor the requested label, but is a manufacturing “snafu,” as it does not focus on the safety or efficacy of the product Specifically, we believe the CRL focused on the manufacturing facility of the drug product manufacturer. The FDA identified deficiencies resulting in a Form 483, which is a list of conditions or practices that are required to be resolved prior to the approval of PEDMARK.¹⁵

68. Further, an April 4, 2021 *Simply Wall St.* article described analysts as "optimistic" about Fennec's potential to turn a profit in 2022, as illustrated by the following graphic.¹⁶



¹⁵ Charles C. Duncan, Ph.D., Pete Stavropoulos, Ph.D., *4Q20 – Adequate Cash and One Step Closer on PEDMARK Re-Filing in CIHL – Can You Hear Me?*, Cantor Fitzgerald (Mar. 30, 2021).

¹⁶ *Analysts Are Optimistic We'll See A Profit From Fennec Pharmaceuticals Inc.* (NASDAQ:FENC), Simply Wall St. (Apr. 4, 2021), <https://www.yahoo.com/video/analysts-optimistic-well-see-profit-095458127.html>

Materially False and Misleading Statements Issued During the Class Period

69. The Class Period begins on May 28, 2021, when Fennec issued a press release announcing the submission of the Resubmitted Pedmark NDA with the FDA (the “May 2021 Press Release”). That press release stated, *inter alia*, that “[t]he resubmission for PEDMARK follows receipt of final minutes from a Type A meeting with the FDA[,]” and that, “[i]mportantly, the [CRL] received on August 10, 2020 referred to deficiencies with the facility of the drug product manufacturer[,]” thereby indicating to investors that the Resubmitted PEDMARK NDA had resolved those issues.

70. Following the issuance of the May 28, 2021 press release, Fennec’s stock price increased over 13% to open at \$7.78 on June 1, 2021.

71. The statements contained in ¶69 above were materially misleading because they omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) manufacturing deficiencies still existed at the Cockeysville Facility at the time of the PEDMARK resubmission; (ii) Defendants had not verified that deficiencies were resolved; (iii) Defendants had not procured evidence establishing that “the methods used in manufacturing the drug and the controls used to maintain the drug’s quality are adequate to preserve the drug’s identity, strength, quality, and purity,” as FDA regulations require for approval; (iv) therefore, Defendants had not established a basis for approval of the Resubmitted PEDMARK NDA; (v) accordingly, the regulatory and commercial prospects of the Resubmitted PEDMARK NDA were overstated; and (vi) as a result, the Company’s public statements were materially false and misleading at all relevant times.

72. On June 22, 2021, Fennec issued a press release announcing that the FDA “has accepted for filing the resubmission of its [NDA] for PEDMARK™,” and reiterated that “[t]he

Complete Response Letter (CRL) received on August 10, 2020, referred to deficiencies with the facility of the drug product manufacturer[.]" thereby indicating to investors that the Resubmitted PEDMARK NDA had resolved those issues.

73. Following the June 22, 2021 press release, Fennec's stock price increased nearly 10% to close at \$7.29 on June 24, 2021.

74. The statements contained in ¶72 were materially misleading because they omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) manufacturing deficiencies still existed at the Cockeysville Facility as of June 22, 2021; (ii) Defendants had not verified that deficiencies were resolved; (iii) Defendants had not procured evidence establishing that "the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity," as FDA regulations require for approval; (iv) therefore, Defendants had not established a basis for approval of the Resubmitted PEDMARK NDA; (v) accordingly, the regulatory and commercial prospects of the Resubmitted PEDMARK NDA were overstated; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

75. PII received another Form 483 for each of its facilities based on inspections which took place between July 26, 2021 and September 29, 2021.¹⁷

76. These inspections identified numerous violations of good manufacturing practices, including residue on the outside of bottles, cracked vials, unsterilized manufacturing suites, improper glove protocol, and numerous vials of PEDMARK left ***unsecured and uncapped*** while

¹⁷ Shirshendu Deb FDA, Marcellinus Dordunoo FDA, Kathleen Jordan FDA, Viviana Matta FDA, 483 Pharmaceutics International Sep 2021 (Sept. 29, 2021), <https://fdazilla.com/store/form483/3006503102-20210929>.

the Cockeysville Facility suffered a fire alarm. *Id.*

77. FE3 worked at PII from October 2020 until May 13, 2022. FE3 was based at the Cockeysville Facility and reported to Vishnu Dwadasi, Head of Project Management at PII.

78. FE3, who worked on the Fennec project, was at PII when the Cockeysville Facility was inspected by the FDA in 2021 and subsequently received a Form 483 that impacted Fennec's NDA for PEDMARK.

79. FE3 explained that after the inspection, PII provided Fennec with the FDA's audit inspection report, which FE3 referred to as the EIR [Establishment Inspection Report].

80. In addition, FE3 stated that PII provided Fennec with the Form 483 that was issued by the FDA that listed deficiencies founds during the inspection.

81. As such, FE3 was able to confirm that Fennec knew, post-inspection, what PII deficiencies were found by the FDA.

82. On August 10, 2021, Fennec issued a press release announcing the Company's second quarter 2021 financial results and providing a business update (the "2Q21 Press Release"). That press release stated, in relevant part, that "*[t]he decrease in cash and cash equivalents between June 30, 2021 and December 31, 2020, is the result of expenses related to the development and preparation of [inter alia] our [NDA] resubmission of PEDMARK™[.]*" and that "*R&D [research and development] expenses decreased by \$0.3 million for the three months ended June 30, 2021 over the same period in 2020 as the Company's development activities shifted back to essential activities in preparation for the launch of PEDMARK™.*"

83. The 2Q21 Press Release also quoted Defendant Raykov, who represented: "We are pleased that the FDA has accepted our PEDMARK™ NDA resubmission, and as we work closely with the Agency through the review process, *we are also focusing on essential activities in*

preparation to bring this important treatment to children receiving cisplatin chemotherapy].J”

84. The statements contained in ¶¶82-83 above were materially misleading because they omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) manufacturing deficiencies still existed at the Cockeysville Facility as of August 10, 2021; (ii) Defendants had not verified that deficiencies were resolved; (iii) Defendants had not procured evidence establishing that “the methods used in manufacturing the drug and the controls used to maintain the drug’s quality are adequate to preserve the drug’s identity, strength, quality, and purity,” as FDA regulations require for approval; (iv) therefore, Defendants had not established a basis for approval of the Resubmitted PEDMARK NDA; (v) accordingly, the regulatory and commercial prospects of the Resubmitted PEDMARK NDA were overstated; (vi) Defendants’ “*development activities*” and/or “*essential activities*” were far more likely to result in another Form 483 and another denial of the Company’s PEDMARK NDA, and not the “*launch of PEDMARK*” or “*bring[ing] this important treatment to children receiving cisplatin chemotherapy*” as claimed; and (vii) as a result, the Company’s public statements were materially false and misleading at all relevant times.

85. Also on August 10, 2021, Fennec filed a quarterly report on Form 10-Q with the SEC, reporting the Company’s financial and operating results for the quarter ended June 30, 2021 (the “2Q21 10-Q”). That filing stated, *inter alia*, that “*[i]n the fourth quarter of 2020, we engaged in a Type A meeting with the FDA concerning the CRL [for the Initial Pedmark NDA] that we believe was constructive and collaborative.*”

86. The 2Q21 10-Q also assured investors that “*[c]urrent liabilities decreased sharply, primarily due to the completion of manufacturing and pre-commercialization activities and regulatory expenses associated with the PEDMARK™ NDA resubmission[J]*” and that “*[w]e*

have decreased our research and development expenses related to PEDMARK™ as our efforts have shifted to pre-commercialization activities after the NDA resubmission in May 2021.”

87. Appended as an exhibit to the 2Q21 10-Q were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”), wherein the Individual Defendants certified that “[t]he information contained in the [2Q21 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company.”

88. The statements contained in ¶¶85-87 above were materially misleading because they omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) manufacturing deficiencies still existed at the Cockeysville Facility as of August 10, 2021; (ii) Defendants had not verified that deficiencies were resolved; (iii) Defendants had not procured evidence establishing that “the methods used in manufacturing the drug and the controls used to maintain the drug’s quality are adequate to preserve the drug’s identity, strength, quality, and purity,” as FDA regulations require for approval; (iv) therefore, Defendants had not established a basis for approval of the Resubmitted PEDMARK NDA; (v) Defendants’ characterization of the Type A meeting as “*constructive and collaborative*” minimized the high likelihood of another Form 483 and/or another denial of the Company’s PEDMARK NDA and indicated to investors that the Resubmitted PEDMARK NDA had resolved the still-existent PII manufacturing facility issues; (vi) Defendants’ alleged “*completion of manufacturing and pre-commercialization activities*” indicated to investors that the Resubmitted PEDMARK NDA resolved the still-existent PII manufacturing facility issues; (vii) Defendants’ claim that “[c]urrent liabilities decreased sharply, primarily due to the completion of manufacturing and pre-commercialization activities” indicated to investors that the Resubmitted PEDMARK NDA had resolved the still-existent PII manufacturing facility issues; (viii)

Defendants' claim that Fennec's "*efforts have shifted to pre-commercialization activities after the NDA resubmission in May 2021*" indicated to investors that the Resubmitted PEDMARK NDA had resolved the still-existent PII manufacturing facility issues; (ix) accordingly, the regulatory and commercial prospects of the Resubmitted PEDMARK NDA were overstated; and (x) as a result, the Company's public statements were materially false and misleading at all relevant times, and did not fairly present the truth regarding Fennec's current operations.

89. On August 11, 2021, Fennec presented at the 2021 Wedbush PacGrow Healthcare Conference ("Wedbush Conference"), and Defendant Raykov stated, with respect to Fennec's manufacturing deficiencies, "*we believe that has been addressed*" and cited "*inspections and consultants*" as well as "*our quality department that feels strongly that the facility is ready for resubmission otherwise it would not be submitted.*" Expanding on this point, Defendant Raykov claimed that because "*the FDA accepted the application for resubmission*", the manufacturing facility no longer posed a threat to FDA approval of PEDMARK.

90. Also during the Wedbush Conference, Defendant Raykov stated that Fennec's 2020 CRL "had to do with the facility of our ... third-party drug product facility where we manufacture our drug product *and has now we believe been resolved.*"

91. In addition, Defendant Raykov claimed that Fennec had a backup manufacturer lined up in the event that PII was once again sidelined by the FDA:

We do have an alternative supplier that we have been working with as well. As you can imagine, we are a low volume manufacturer ... *Lucky for us, we have a second supplier, and we have been working with them for the last several months.* However, from a timing perspective, we are still better off with our original supplier so we are very hopeful that by PDUFA date we are in a position to pass the inspection. I really don't want to get into the details about the pre-approval proof of inspection because you create expectations.

92. The statements contained in ¶¶89-91 above were materially misleading because they omitted the following material information necessary to make the statements not misleading

under the circumstances in which they were made: (i) manufacturing deficiencies still existed at the Cockeysville Facility as of August 11, 2021; (ii) Defendants had failed to conduct adequate due diligence into PII; (iii) the FDA’s acceptance of the Resubmitted PEDMARK NDA did not waive the possibility of another Form 483 and/or another denial of the Company’s PEDMARK NDA; (iv) Defendants, under FDA regulations, were not entitled to simply defer to an unapproved “backup” manufacturer when PII received another Form 483 for the reasons discussed at ¶¶35-36 above; (v) Defendants had not verified that deficiencies were resolved; (vi) Defendants had not procured evidence establishing that “the methods used in manufacturing the drug and the controls used to maintain the drug’s quality are adequate to preserve the drug’s identity, strength, quality, and purity,” as FDA regulations require for approval; (vii) therefore, Defendants had not established a basis for approval of the Resubmitted PEDMARK NDA; (viii) accordingly, the regulatory and commercial prospects of the Resubmitted PEDMARK NDA were overstated; and (ix) as a result, the Company’s public statements were materially false and misleading at all relevant times.

93. On September 22, 2021, Fennec presented at the Oppenheimer Fall Healthcare Life Sciences & MedTech Summit (“Oppenheimer Summit”). At the Oppenheimer Summit, Defendant Raykov refused to provide “granularity” concerning Fennec’s manufacturing practices while touting PII as follows:

You never want to be overly confident with anything when it comes to the FDA. However, when we made our refiling we did not do this in a vacuum. Just to give a sense for everyone, typically in this process, last year we received on a 483 observations related to our third party manufacturer and it had nothing to do with our product, they were strictly related to how the third party manufacturer operates and conducts business within GMP conditions. To give a sense to everyone as well, we are not their first customer; ***this is a well-established plant that has been around for a long time.*** We are one of many companies that has received a CRL so hopefully this backlog of CRLs will get cleared, and a year has passed which is really important because in that period of time the plant has made really

significant improvements to how they conduct themselves, how they manage their business, the type of people that are operating there, and the leadership and they have also made some capital improvements as well, so we think the plant is in good shape to refile, and we did not do this in a vacuum, we did this based on communication from the plant, we did this in speaking with the FDA on a regular basis – all the improvements they have made, and so the last remaining piece is really for the FDA to conduct a preapproval inspection, and once that's completed, hopefully the plant passes that, and our application, as well as many others, are allowed to go forward.

94. During the Oppenheimer Summit, Defendant Raykov stated, in regard to PEDMARK, that “*we expect approval early next year.*”

95. The statements contained in ¶¶93-94 above were materially misleading because they omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) manufacturing deficiencies still existed at the Cockeysville Facility as of September 22, 2021; (ii) Defendants had failed to conduct adequate due diligence into PII, which had a documented history of significant manufacturing issues; (iii) PII had not made “*significant improvements*” sufficient to avoid another Form 483 and/or another denial of the Company’s PEDMARK NDA; (iv) Defendants’ discussions with the FDA did not waive the possibility of another Form 483 and/or another denial of the Company’s PEDMARK NDA; (v) Defendants had not verified that deficiencies were resolved; (vi) Defendants had not procured evidence establishing that “the methods used in manufacturing the drug and the controls used to maintain the drug’s quality are adequate to preserve the drug’s identity, strength, quality, and purity,” as FDA regulations require for approval; (vii) therefore, Defendants had not established a basis for approval of the Resubmitted PEDMARK NDA or any expectation of same; (viii) accordingly, the regulatory and commercial prospects of the Resubmitted PEDMARK NDA were overstated; and (ix) as a result, the Company’s public statements were materially false and misleading at all relevant times.

96. On September 29, 2021, Fennec presented at the 7th Cantor Global Healthcare

Conference, during which Defendant Raykov stated that –

The action date is November 27th, we are not going to pre-empt that. Once the agency has done its pre-approval inspection, they issue something called an EIR, again, going back to what happened last time, *the EIR may or may not contain 483 observations and the keys to those observations, to the extent there are any, the key is that those observations are not critical*, so that this plant can pass GMP pre-approval inspections so we can start selling our drug from – we are not the only company coming out of this plant..some of our peers, breakthrough therapy designations and other important products, have been affected by this and so we are hopeful, this is an important plant for the US, and we are hopeful this gets sorted out on November 27th. *If it does not for whatever reason and the plant does not pass again preapproval inspection, we have a plan B, we have been lucky enough to find during the COVID times a second manufacturer, we've already manufactured the same formulation*, additional registration batches there to prove stability, so there is more of a timing gap – this first plant allows us to get to market first, but I believe, if for whatever reason November 27th is not – then we can refile a week, maybe three to five month delay, the application with the second plant.

97. The statements contained in ¶96 above were materially misleading because they omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) critical manufacturing deficiencies sufficient to warrant rejection of the Resubmitted PEDMARK NDA still existed at the Cockeysville Facility as of September 29, 2021; (ii) Defendants had failed to conduct adequate due diligence into PII; (iii) the FDA's acceptance of the Resubmitted PEDMARK NDA did not waive the possibility of another Form 483 and/or another denial of the Company's PEDMARK NDA; (iv) Defendants, under FDA regulations, were not entitled to simply defer to an unapproved "backup" manufacturer when PII received another Form 483 for the reasons discussed at ¶¶35-36 above, and Defendants dramatically downplayed the complexity changing manufacturers, and particularly of changing manufacturing sites; (v) Defendants had not verified that deficiencies were resolved; (vi) Defendants had not procured evidence establishing that "the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity," as FDA regulations require for approval; (vii) therefore,

Defendants had not established a basis for approval of the Resubmitted PEDMARK NDA; (viii) accordingly, the regulatory and commercial prospects of the Resubmitted PEDMARK NDA were overstated; and (ix) as a result, the Company's public statements were materially false and misleading at all relevant times.

98. On November 10, 2021, Fennec issued a press release providing a business update and announcing third quarter 2021 ("3Q21") financial results. "[t]he **decrease** in cash and cash equivalents between September 30, 2021, and June 30, 2020 **is the result of expenses related to the development and preparation of [inter alia] the NDA resubmission** of PEDMARK™[,] and that "R&D expenses decreased by \$0.2 million for the three months ended September 30, 2021 over the same period in **2020 as the Company's development activities shifted back to essential activities in preparation for the launch of PEDMARK™**".

99. The 3Q21 Press Release also quoted Defendant Raykov, who represented that "**[w]e are focused on essential activities in preparation to bring this important treatment to children receiving cisplatin chemotherapy[.]**"

100. The statements contained in ¶¶98-99 were materially misleading because they omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) manufacturing deficiencies still existed at the Cockeysville Facility as of November 10, 2021; (ii) Defendants had not verified that deficiencies were resolved; (iii) Defendants had not procured evidence establishing that "the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity," as FDA regulations require for approval; (iv) therefore, Defendants had not established a basis for approval of the Resubmitted PEDMARK NDA; (v) accordingly, the regulatory and commercial prospects of the Resubmitted PEDMARK

NDA were overstated; (vi) Defendants’ “*development activities*” and/or “*essential activities*” were far more likely to result in another Form 483 and another denial of the Company’s PEDMARK NDA, and not the “*launch of PEDMARK*” or “*bring[ing] this important treatment to children receiving cisplatin chemotherapy*” as claimed; and (vii) as a result, the Company’s public statements were materially false and misleading at all relevant times.

101. Also on November 10, 2021, Fennec filed a quarterly report on Form 10-Q with the SEC, reporting the Company’s financial and operating results for the quarter ended September 30, 2021 (the “3Q21 10-Q”). The 3Q21 10-Q contained the same statements as referenced in ¶85 above regarding the purportedly “***constructive and collaborative***” Type A meeting that the Company held with the FDA regarding the deficiencies identified to the Company by the FDA in the CRL for the Initial Pedmark NDA, as well as the regulatory milestones achieved for the Resubmitted Pedmark NDA.

102. The 3Q21 10-Q also assured investors that “***[c]urrent liabilities decreased primarily due to the reduction in manufacturing and regulatory expenses associated with the PEDMARK™ NDA resubmission[,]***” and that “***[w]e have decreased our research and development expenses related to PEDMARK™ as our efforts have shifted to pre-commercialization activities after the NDA resubmission in May 2021.***”

103. Appended as an exhibit to the 3Q21 10-Q were substantively the same SOX certifications as referenced in ¶87 above, signed by the Individual Defendants.

104. The statements contained in ¶¶101-103 were materially misleading because they omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) manufacturing deficiencies still existed at the Cockeysville Facility as of November 10, 2021; (ii) Defendants had not verified that deficiencies

were resolved; (iii) Defendants had not procured evidence establishing that “the methods used in manufacturing the drug and the controls used to maintain the drug’s quality are adequate to preserve the drug’s identity, strength, quality, and purity,” as FDA regulations require for approval; (iv) therefore, Defendants had not established a basis for approval of the Resubmitted PEDMARK NDA; (v) Defendants’ characterization of the Type A meeting as “*constructive and collaborative*” minimized the high likelihood of another Form 483 and/or another denial of the Company’s PEDMARK NDA and indicated to investors that the Resubmitted PEDMARK NDA had resolved the still-existent PII manufacturing facility issues; (vi) Defendants’ claim that “[c]urrent liabilities decreased primarily due to the reduction in manufacturing and regulatory expenses associated with the PEDMARK™ NDA resubmission[,]” indicated to investors that the Resubmitted PEDMARK NDA had resolved the still-existent PII manufacturing facility issues; (vii) Defendants’ claim that Fennec’s “*efforts have shifted to pre-commercialization activities after the NDA resubmission in May 2021*” indicated to investors that the Resubmitted PEDMARK NDA had resolved the still-existent PII manufacturing facility issues; (viii) accordingly, the regulatory and commercial prospects of the Resubmitted PEDMARK NDA were overstated; and (ix) as a result, the Company’s public statements were materially false and misleading at all relevant times, and did not fairly present the truth regarding Fennec’s current operations.

105. Analyst reaction to Defendants’ continued distortions and omissions confirms their efficacy. A report issued on November 10, 2021 by Maxim Group confidently stated, on the basis of Defendants’ representations, that “***[w]e believe the CMC (Chemistry, Manufacturing and***

Controls) issues have since been fully resolved and the strength of the clinical and safety data ought to support approval.”¹⁸

The Truth Emerges

106. On November 29, 2021, Fennec issued a press release announcing that it expected to receive a CRL from the FDA for the Pedmark NDA because of certain deficiencies identified at the manufacturing facility of the Company’s drug product manufacturer. Specifically, that press release stated, in relevant part:

Fennec . . . today announced that it expects to receive a [CRL] after the PDUFA target action date of November 27, 2021 from the [FDA] regarding its [NDA] for PEDMARK™ (a unique formulation of sodium thiosulfate), for intravenous administration for the prevention of ototoxicity associated with cisplatin chemotherapy in pediatric patients \geq 1 month to 18 years of age with localized, non-metastatic, solid tumors.

The FDA has indicated that, following a recent completion of a pre-approval inspection of the manufacturing facility of our drug product manufacturer, deficiencies have been identified. Once the official CRL is received, the Company plans to request a Type A meeting to discuss the deficiencies and steps required for the resubmission of the NDA for PEDMARK™.

107. On this news, Fennec’s common share price fell \$4.86 per share, or 50.41%, to close at \$4.78 per share on November 29, 2021.

108. Analysts at Cantor Fitzgerald downgraded their rating to Neutral from Overweight and lowered their PT to \$7 from \$13 on FENC shares, adding that, “as this is the second time a manufacturing deficiency has arisen within the last 18 months, we can no longer consider it a “black swan” event, as we did in response to the CRL in 2020.”¹⁹

¹⁸ Naureen Quibria, Ph.D., *We’re Optimistic into PDUFA on 11/27 – Maintain Buy*, MAXIM GROUP (Nov. 10, 2021).

¹⁹ Charles C. Duncan, Ph.D., Pete Stavropoulos, Ph.D., *Deafening Sound of Silence – FDA CRL Coming Soon for PEDMARK Due to Contract Manufacturer Non-Compliance?*, Cantor Fitzgerald (Nov. 29, 2021).

109. Writing at Endpoint News on November 29, 2021, Paul Schloesser noted that “[a]t the time of the company’s first CRL on Pedmark, CEO Rosty Raykov told investors there were no clinical safety or efficacy problems and an additional trial was not required, ***but when pushed on the Form 483 the biotech received and what issues had to be resolved, Raykov demurred from the issue.*** That time, Fennec’s stock price fell more than 35%.”²⁰

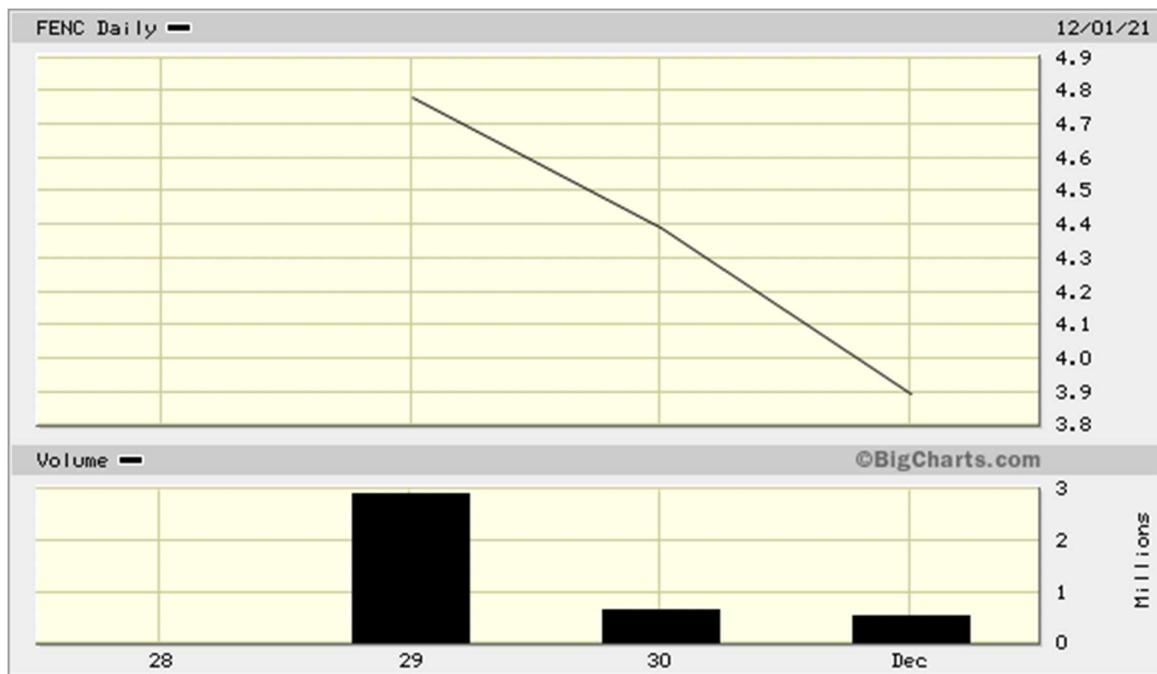
110. On November 30, 2021, Fennec issued a press release confirming “***that it received a [CRL] on November 29, 2021 from the [FDA] . . . regarding its [Pedmark NDA,]***” which “***was issued as a result of identified manufacturing deficiencies which need to be satisfactorily resolved before the Pedmark NDA can be approved.***” In addition, Defendant Raykov noted that while Fennec “***will work closely with [its] current manufacturer as well as the FDA to fully address the issues raised in the letter[,] we continue to advance our second drug product manufacturing facility.***”

111. Naureen Quibria, who had been bullish on FENC, wrote on November 30 that “the CRL was a surprising setback for Fennec, ***as we believed the prior manufacturing deficits had been fully resolved.***”²¹

112. As a result of the news on November 29 and 30, the Company’s stock price plummeted over **59%** to close at \$3.89 on December 1, 2021, after three days of heavy trading. To date, the FDA still has not approved PEDMARK.

²⁰ Paul Schloesser, *More manufacturing issues: Fennec preps for second CRL for potential hearing loss drug*, Endpoint News (Nov. 29, 2021): <https://endpts.com/more-manufacturing-issues-fennec-preps-for-second-crl-for-potential-hearing-loss-drug/>

²¹ Naureen Quibria, Ph.D., *Receives Unexpected CRL, NDA Resubmission Could Occur as Soon as 1Q22; Lowering PT to \$10*, MAXIM GROUP (Nov. 30, 2021).



113. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

ADDITIONAL SCIENTER ALLEGATIONS

114. ***Fennec had very few employees.*** According to an April 2019 article in the *Triangle Business Journal*, Fennec's "lean and mean" company structure included "only 3 employees, Andrade as CFO, CEO Rostislav Raykov and a controller."²² Moreover, Defendant Andrade boasted that the Company had "been careful to raise only enough capital to reach milestones" related to PEDMARK.²³

115. ***Fennec could not risk another CRL with overly fulsome disclosures because its***

²² Seth Thomas Gullledge, *This \$90M public company is "set up" for sale, CFO says*, AMERICAN CITY BUSINESS JOURNALS (Apr. 25, 2019), <https://www.bizjournals.com/triangle/news/2019/04/25/this-90m-public-company-is-set-up-for-sale-cfo.html>.

²³ *Id.*

commercialization funding was directly tied to FDA approval. The April 2019 *Triangle Business Journal* article reported that the Company's commercialization efforts would be funded by a \$12.5 million debt financing deal with Bridge Bank. *However, this funding was contingent upon the approval of PEDMARK.*²⁴

116. *Defendants touted their close working relationship with the FDA.* Fennec's November 2020 Press Release quotes Defendant Raykov as stating that "*[w]e are working closely with the FDA and our third-party drug product manufacturer to fully address the CRL[J]*"²⁵ Likewise, the June 2021 Press Release quoted Defendant Raykov as confirming that Defendants will be "*working closely with the FDA through the review process.*" Finally, the August 2021 Press Release likewise quoted Defendant Raykov as affirming that "*we [are] work[ing] closely with the Agency through the review process[J]*" Defendants' close relationship with the FDA compels the conclusion that Defendants were well aware of the manufacturing concerns raised by the Agency prior to the November 2021 CRL.

117. *Defendants Knew Compliance with cGMP was Critical:* Fennec's own SEC filings indicate Defendants' knowledge of the strenuous regulatory process and requirements that had to be met in order for the Company to obtain FDA approval for PEDMARK:

We anticipate substantial regulatory review prior to the commercialization of PEDMARK™.

* * *

The production and manufacture of our product candidate and our research and development activities are subject to significant regulation for safety, efficacy and quality by various governmental authorities around the world.

* * *

The FDA reviews an NDA to determine, among other things, whether the

²⁴ *Id.*

²⁵ *Fennec Pharmaceuticals Announces Third Quarter 2020 Financial Results and Provides Business Update*, FENNEC PHARMACEUTICALS, INC. (Nov. 16, 2020), <https://investors.fennecpharma.com/news-releases/news-release-details/fennec-pharmaceuticals-announces-third-quarter-2020-financial>.

drug is safe and effective for its intended use and *whether the facility in which it is manufactured, processed, packaged or held meets standards* designed to assure the product's continued safety, quality and purity.

* * *

[D]rug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and register or obtain permits or licenses in states where they do business, and *are subject to periodic unannounced inspections by the FDA and state regulatory authorities* with jurisdiction over their activities *to determine compliance with regulatory requirements.... The failure of a drug manufacturer or any of its third-party contractors to comply* with federal or state laws or regulations *may subject the drug manufacturer to* possible legal or regulatory action, such as *an untitled letter, warning letter, recall, suspension of manufacturing or distribution or both*, suspension of state permit or license, seizure of product, import detention, injunctive action, and civil and criminal penalties.²⁶

118. Defendants Were Uniquely Motivated to Preserve their Exorbitant Compensation. Defendant Raykov's personal compensation ballooned from an initial salary of \$140,000 in 2009 to \$458,402 in 2021, even though the Company had no significant revenue.²⁷ When bonuses and option awards are factored in, Defendant Raykov's total compensation swelled to \$3,410,325 in 2021.²⁸ Defendant Andrade also saw a steady increase from his initial salary of \$165,000 beginning in 2015 to the \$332,075 he drew in 2021.²⁹ For 2021, Defendant Andrade's total compensation was \$1,491,439.³⁰

119. Fennec's chief commercial officer abruptly resigned in the wake of its 2021 CRL.

²⁶ 2018 10-K, 2019 10-K, 2020 10-K, 2021 10-K.

²⁷ Seth Thomas Guldedge, *With stock down 68% in past year, RTP outfit's CEO, CFO enjoy 15% bump in compensation*, AMERICAN CITY BUSINESS JOURNALS (Apr. 24, 2019) <https://www.bizjournals.com/triangle/news/2019/04/24/with-stock-down-68-in-past-year-rtp-outfits-ceo.html>; Fennec Pharmaceuticals, Inc., Annual Report (Form 10-K) (Feb. 28, 2022) ("2021 10-K").

²⁸ 2021 10-K.

²⁹ <https://www.bizjournals.com/triangle/news/2019/04/24/with-stock-down-68-in-past-year-rtp-outfits-ceo.html>; 2021 10-K.

³⁰ 2021 10-K.

On January 31, 2022, Fennec issued a press release announcing “that Shubh Goel, the Company’s chief commercial officer, has tendered her resignation and will depart Fennec in late February [2022].” Goel was hired in that role in September 2019.

CLASS ACTION ALLEGATIONS

120. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Fennec securities during the Class Period (the “Class”); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

121. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Fennec securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Fennec or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

122. Plaintiff’s claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants’ wrongful conduct in violation of federal law that is complained of herein.

123. Plaintiff will fairly and adequately protect the interests of the members of the Class

and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

124. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Fennec;
- whether the Individual Defendants caused Fennec to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Fennec securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

125. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

126. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;
- Fennec securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Fennec securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

127. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

128. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

129. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

130. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

131. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other

members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Fennec securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Fennec securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

132. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Fennec securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Fennec's finances and business prospects.

133. By virtue of their positions at Fennec, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant

knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

134. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Fennec, the Individual Defendants had knowledge of the details of Fennec's internal affairs.

135. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Fennec. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Fennec's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Fennec securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Fennec's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Fennec securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

136. During the Class Period, Fennec securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Fennec securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the

other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Fennec securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Fennec securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

137. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

138. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

139. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

140. During the Class Period, the Individual Defendants participated in the operation and management of Fennec, and conducted and participated, directly and indirectly, in the conduct of Fennec's business affairs. Because of their senior positions, they knew the adverse non-public information about Fennec's misstatement of income and expenses and false financial statements.

141. As officers and/or directors of a publicly owned company, the Individual

Defendants had a duty to disseminate accurate and truthful information with respect to Fennec's financial condition and results of operations, and to correct promptly any public statements issued by Fennec which had become materially false or misleading.

142. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Fennec disseminated in the marketplace during the Class Period concerning Fennec's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Fennec to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Fennec within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Fennec securities.

143. Each of the Individual Defendants, therefore, acted as a controlling person of Fennec. By reason of their senior management positions and/or being directors of Fennec, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Fennec to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Fennec and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

144. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Fennec.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule

23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

- B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and
- D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: June 23, 2022

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CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on June 23, 2022, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to counsel of record.

/s/ Louis C. Ludwig

Louis C. Ludwig